AUG 16 2004

K032742

SECTION 11
510(k) SUMMARY

General Information

This 510(k) is to provide notification of substantial equivalence for Advanced Medical Solutions Ltd's Silver Foam Wound Dressing, which is substantially equivalent to currently marketed devices intended for wound care.

Submitted by:	Advanced Medical Solutions Ltd., Road Three, Winsford Industrial Estate, Winsford, Cheshire, CW7 3PD, England
Contact:	Mr. John Greenham Regulatory Affairs Manager
Telephone:	44 (0)1606 545569
Fax:	44 (0)1606 863600
e-mail:	john.greenham@admedsol.com

Date prepared:	04 August 2004
Classification:	Dressing, wound and burn occlusive (21 CFR 878.4020)
Trade name:	Silver Foam Adhesive and Non-Adhesive Wound Dressings
Common name:	Topical Wound Dressings
Predicate devices:	K022416 Contreet® Foam Dressing, Adhesive and Non-Adhesive
Indications for use:	Advanced Medical Solutions Ltd's **(Brand name*) Silver Foam Adhesive and Non-Adhesive Wound Dressings** are indicated for moderately to heavily exuding, partial to full thickness wounds, including: pressure ulcers leg ulcers; diabetic foot ulcers; graft wounds and donor sites; skin tears; first and second-degree burns; surgical wounds; lacerations and abrasions.

Product Description:

(Brand name*) Silver Foam Adhesive and Non-Adhesive Wound Dressings are sterile, extremely absorbent, conformable, and semi-permeable to moisture vapour, and assist in maintaining a moist environment for optimal wound healing.

(Brand name*) Silver Foam Adhesive and Non-Adhesive Wound Dressings contain nominally 1% ionic silver (silver sodium hydrogen zirconium phosphate); the action of which protects the dressing from bacterial colonisation, and provides an effective barrier to bacterial penetration. The antimicrobial properties of the dressing are effective for up to 7 days, as demonstrated in vitro, against bacterial and fungal strains known to be detrimental to wound healing, such as; Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Candida albicans, Streptococcus pyogenes, Staphylococcus epidermidis, MRSA (Methicillin resistant Staphylococcus aureus) MRSE (Methicillin resistant Staphylococcus epidermidis), and VRE (Vancomycin resistant Enterococcus faecium).

The antibacterial effect in the **(Brand name*) Silver Foam Adhesive and Non-Adhesive Wound Dressings** supports the reduction of odour caused by microorganisms absorbed in wound exudate.

(Brand name*) Silver Foam Adhesive and Non-Adhesive Wound Dressings may be used with a compression bandage.

Statement of technological characteristics of the subject Device compared to the predicate device:

The **(Brand name*) Silver Foam Adhesive and Non-Adhesive Wound Dressings** are substantially equivalent to Contreet® Foam Adhesive and Non-Adhesive Dressings.

(Brand name*) Silver Foam Adhesive and Non-Adhesive Wound Dressings and the predicate device have the same intended use and have almost identical indications for use (e.g. partial and full thickness wounds, pressure ulcers, donor sites, leg ulcers, diabetic foot ulcers, second degree burns, post-operative wounds and abrasions).

(Brand name*) Silver Foam Adhesive and Non-Adhesive Wound Dressings and the predicate device consist of an outer moisture vapour permeable hydrophobic membrane and a hydrophilic foam that contains the same percentage of silver. The adhesive variants incorporate an adhesive border. Both devices are provided sterile to the user, for single use, and both devices incorporate silver, to provide an effective barrier to bacterial penetration.

Both devices are biocompatible, exhibit absorbent properties, assist in maintaining a moist environment for optimal wound healing, permit intact removal, have a similar method of affixation, and have the same recommended frequency of dressing changes.

Both devices shave a similar range of product sizes, are sterilised by gamma irradiation, and have similar contraindications.

Although there are some differences between the devices, these differences are minor and raise no new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 6 2004

Mr. John E. Greenham
Regulatory Affairs Manager
Advanced Medical Solutions Ltd.
Road Three, Winsford Industrial Estate,
Winsford,
Cheshire, CW7 3PD U.K.

Re: K032742
Trade/Device Name: Silver Foam Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 23, 2004
Received: July 6, 2004

Dear Mr. Greenham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K032742**

Device Name: Advanced Medical Solutions Ltd's
Silver Foam Wound Dressing

Indications For Use:

Advanced Medical Solutions Ltd's Silver Foam Wound Dressings are indicated for moderately to heavily exuding, partial to full thickness wounds, including:

- pressure ulcers
- leg ulcers
- diabetic foot ulcers
- graft wounds and donor sites
- skin tears
- first and second degree burns
- surgical wounds
- lacerations and abrasions.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K032742